

CHAPTER 28: SUMMARY OF SAFETY AND EFFECTIVENESS

1.0 Use

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neonatal patients and/or ST segment of adult patients.

1.1 What it is

CentralVue Software is a centralized patient monitoring application that executes on an NT Workstation and operates on data received from other networked medical devices.

- Part of body or type of tissue interacted with: None, all patient connections are made by other remote devices.
- Frequency of use: As prescribed by clinician.
- Physiological purpose: To gain information for treatment, to monitor adequacy of treatment, or to rule out causes of symptoms.
- Prescription versus over-the-counter: CentralVue Software is a prescription device.

1.2 What it does

CentralVue Software displays physiologic waves and parameters, provides retrospective review of physiologic waves and parameters and provides the secondary annunciation of alarms for up to eight patients at a centralized location. CentralVue Software embeds STAR ST Segment and Arrhythmia analysis for up to eight patients. CentralVue Software can format data for compliant strip chart recorders such as the CentralVue Recorder.

3.0 How it Works

3.1 System Requirements

CentralVue Software can only be used on NT Workstations that are specified in the labeling or that are subsequently qualified by Hewlett-Packard.

3.2 How CentralVue Software Functions

CentralVue Software is a software device that consists of monitoring applications, STAR ST Segment and Arrhythmia monitoring software that run in the monitoring mode. In addition, system management software runs when in the non-monitoring mode.

Monitoring mode applications provide patient monitoring functionality. STAR ST Segment and Arrhythmia monitoring is a subset of the patient monitoring software that runs in monitoring mode.

Non-monitoring mode software provides the start-up, shut-down, installation, and other system management functions.

1.3 Who Uses it on Whom

CentralVue Software is intended to be used by trained clinicians to monitor cardiac function in neonatal, pediatric, or adult patients.

1.4 Who Prescribes it

In the USA, Federal law restricts CentralVue Software to sale by or on the order of a physician.

1.5 Where is it Used

CentralVue Software is intended to be used in a professional health care facility.

CentralVue Software is not intended for home use.

2.0 Indications for Use

The indications for use of the Hewlett-Packard CentralVue Software are:

- Condition: the clinician decides to centrally monitor up to 8 adult, pediatric, and/or neonatal patients;

and for the embedded STAR:

- Condition: the clinician decides to monitor cardiac arrhythmia of adult, pediatric, and/or

4.0 Summary of Major Features

Key features of CentralVue Software are shown in the patient monitoring Main Screen and All Controls menu:

Main Screen - up to 8 patients, up to 2 waves per patient, maximum of 16 waves per screen.

Patient Management - easy patient admit, discharge, bed transfer, change of monitoring equip-

ment from bedside to telemetry, and customization of the Main Screen patient sector.

Alarm Management and Setup - separate adjustment of arrhythmia and ST segment monitoring alarms for each patient.

Patient Data Review - access to stored patient data for alarms, trends, events, full disclosure waveform, and ST segment review.

Configuration and Support - direct access to sound volume control, device status and error information, and service support information; clinical password access to monitor default configurations; support password access to a wide range of service support functions.

5.0 How it Compares to other Devices

CentralVue Software is similar to the predicates in that it has the same use, features, and specifications.

6.0 How was it Verified and Validated

The development team tested the device during development by performing unit and integration testing. STAR ST Segment and Arrhythmia monitoring software embedded in CentralVue Software was tested to assure that it performed as disclosed in an earlier submission. When the black box, gray box, white box, and STAR regression tests were completed a separate test group validated that CentralVue Software meets its performance claims and is safe and effective in its intended use.

7.0 How we Know it is Safe and Effective When Used as Labeled

The defined and controlled development processes followed, and the documented test results obtained from extensive testing produces a very high confidence level that the device is safe and effective when used as intended.